75TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
3d Session } { No. 2139

FOOD, DRUG, AND COSMETIC ACT

APRIL 14, 1938.—Committed to the Committee of the Whole House on the state of the Union and ordered to be printed

Mr. LEA, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany S. 5]

The Committee on Interstate and Foreign Commerce, to whom was referred the act (S. 5) to prevent the adulteration, misbranding, and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the United States, for the purposes of safeguarding the public health, preventing deceit upon the purchasing public, and for other purposes, report favorably thereon with an amendment and recommend that the act do pass.

The committee amendment strikes out all of the Senate bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

The act herewith reported is the culmination of more than 5 years of study by your committee.

GENERAL PURPOSES

This act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906, as amended (U. S. C., title 21, secs. 1–15). That act is popularly known as the Wiley pure-food law, because that great pioneer in pure food and drug legislation, Dr. Harvey W. Wiley, led the fight for its enactment.

While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions.

IMPROVEMENTS OVER EXISTING LAW

The measure contains substantially all the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception, and it extends the scope of the law to include cosmetics, therapeutic devices, and certain drugs that now escape regulation.

The principal respects in which the measure differs from the present law are:

The adulteration and misbranding of cosmetics is prohibited.

Therapeutic devices are brought under control.

Drugs intended for diagnosing illness or for remedying underweight or overweight or for otherwise affecting bodily structure or function are subjected to regulation.

New drugs are required to be adequately tested for safety before they are placed on the market.

Reasonable sanitation is required in the production of foods, drugs, and cosmetics.

Foods that are dangerous because of naturally contained poisons rather than added poisons are brought under regulation. The addition of poison to foods is prohibited except where such addition is necessary or cannot be avoided; and in such cases tolerances are provided limiting the amount of added poison to the extent necessary to safeguard the public health.

Where the other provisions of the measure are not effective to control danger to health arising from bacterial contamination of food, temporary license restrictions can be imposed until the difficulty is corrected.

Definitions and standards of identity are provided under which the integrity of food products can be effectively maintained.

Informative labeling of foods as to quality and composition is required for the information and guidance of consumers. Emphasis is placed on the informative labeling of special dietary food, such as that for infants and invalids.

The distinctive name proviso of the present law under which many debased and cheapened foods have escaped control is eliminated.

The provision under which proceedings could be brought against falsely labeled patent medicines only upon evidence to prove that the manufacturer knew his labels were false is eliminated.

Control is set up for drugs which are dangerous to health when taken in the dosage and with the frequency prescribed by the manufacturer in the labeling.

Habit-forming drugs must be labeled with warnings that they are habit forming.

Potent drugs liable to be misused must bear label warnings against probable misuse.

Special safeguards are set up for packaging and labeling deteriorating drugs.

Antiseptics must possess germ-killing power.

Authority is provided for inspection of factories making interstate shipments, without which the law could not be effectively enforced.

Carriers are required to make, available for copying, records showing interstate shipments of suspected articles so that Federal jurisdiction can be established.

Increased penalties are provided for violations.

Authority is given to the Federal courts to restrain violations by injunction.

These and other less important provisions are contained in the bill to make the measure effective for consumer protection without imposing unnecessary burdens on industry.

SECTIONAL ANALYSIS AND EXPLANATION OF CERTAIN CHANGES MADE BY THE COMMITTEE

The changes from the Senate bill made by this committee are in some cases self-explanatory. In other cases a detailed explanation of such changes is contained in the following sectional analysis.

Section 201 is composed of general definitions. Those of food, drug, device, and cosmetic are the same as the definitions in S. 1077, the recently enacted amendment to the Federal Trade Commission Act providing for control of false advertisement of these commodities.

The definition of food is simply a clarification of the definition in the Food and Drugs Act of June 30, 1906. The definition of drug is expanded to include articles used in the diagnosis of disease, and articles other than food intended to affect the structure or any function of the body of man or other animals. These expansions are needed to give jurisdiction over a great number of drugs which are not amenable to control under the present law.

The definitions of device and cosmetic are here provided for the operation of subsequent sections relating specifically to these commodities, which are not covered by the present law. Paragraph (n), outlining the considerations to be taken into account in determining whether labeling is misleading, has the same meaning as a provision in S. 1077 relating to false advertising. Its purpose is obvious. It is applicable to the general misbranding provisions relating to foods, drugs, devices, and cosmetics. One of its more important applications will be discussed in detail in connection with the general misbranding provision on drugs and devices, section 502 (a).

A definition of the term "new drug" is provided for the purpose of applying section 505, a provision intended to require adequate testing of new drugs to determine their safety before they are placed on the market. This is a new provision. The definition of "advertisement" in the Senate bill is omitted, as are subsequent provisions relating to advertising since control of false advertising has been provided through S. 1077.

Section 301 defines prohibited acts. In general this section denies the channels of interstate commerce to products which are adulterated or misbranded or are otherwise unsafe for use. In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.

Section 302 provides a new enforcement procedure for food and drug legislation by authorizing the courts to enjoin violations. This procedure will be particularly advantageous in border-line cases that cannot be settled without litigation. In many such cases it is unfair to the manufacturer to subject him to criminal trial and likewise unfair to the public to have the issue determined under the restrictions

necessarily prevailing in criminal procedure. This remedy should reduce litigation. In some cases it should avoid the hardship and expense to litigants in seizure cases. In many instances seizure is a harsh remedy and should be discouraged or confined to those cases where the public protection requires such action. In many cases, it is believed, the use of injunctions can be used with equal effectiveness and with less hardship. A seizure case finally decided in favor of a defendant leaves him without recourse for his losses, including court costs, storage, and other charges.

Section 303 increases substantially the criminal penalties of the present law which some manufacturers have regarded as substantially a license fee for the conduct of an illegitimate business. Appropriate exemptions are provided for dealers who innocently receive and distribute illegal goods.

Section 304 repeats in substance the seizure provision of the present law but in order to guarantee against unreasonable and arbitrary exercise of this authority it limits to a single interstate shipment, seizure action on misbrandings that are not genuinely serious and that have not been the subject of a prior court decision in favor of the United States. Multiple seizures may be made on adulterations and on misbranding "when the Secretary has probable cause to believe that the misbranded article is dangerous to health or that the labeling of the misbranded article is, in a material respect, false or fraudulent." This represents substantially the administrative policy followed by the Department of Agriculture in the more than 30 years the old law has been enforced.

The language adopted by your committee differs from that of the Senate act in that in the provision above quoted, the words "false and fraudulent" rather than "false or fraudulent" are used. If a misbranding is sufficiently serious to justify the removal of the product from the market to safeguard the consumer against harm, then it is wholly immaterial whether the falsity of the labeling is a matter of gross carelessness or inadvertence, or whether it was grounded on a deliberate intent to deceive. Since the seizure procedure is peculiarly adapted to the enforcement of a consumer-protective law in that it arrests the illegal goods before the consumer is harmed, your committee has been careful to avoid restricting this form of action in cases where there is actual need for its exercise to protect health or prevent fraud.

The committee amendment contains provisions to permit the removal of seizure cases for trial to jurisdictions nearby the claimant's principal place of business. Where multiple seizures involving the same issues are pending, the cases may be consolidated for trial. Under the Senate provision the cases may be tried in the district in which the claimant's principal place of business is located. The committee amendment provides that these transfers may be made to a district in a State adjacent to the State of the claimant's principal place of business.

Your committee deemed it wise to add to this section a new subsection (f), specifically providing that in cases of removal, the trial court shall have the same powers and be subject to the same duties as those of the court in which the seizure was made and in which it otherwise would have been tried.

Section 305 provides that the accused be given a hearing before a criminal proceeding is instituted. This merely requires continuation of a practice that has been followed in the enforcement of the present law. The language has been changed from that of the Senate provision (sec. 7) to make it clear that the kind of hearing contemplated is an informal one, and is not to be a formal preliminary trial of the case before the Secretary. The Senate provision directing the Secretary to certify the facts to the United States Attorney and prescribing that the report should be accompanied by authenticated findings of appropriate officers has been deleted as unnecessary.

Section 306 authorizes the settlement of minor violations by suitable written notice or warning where the public interest will be adequately served by such settlement. Its tendency is to avoid encumbering court dockets with trivial or unnecessary litigation. This specific statement will give definite legislative sanction to the procedure.

Section 307 first specifies that the proceedings under the act shall be by and in the name of the United States, and then contains an important provision that subpenas for witnesses in such proceedings may run throughout the jurisdiction of the United States. Without this provision the trial of seizure and injunction cases would be handicapped, and in some cases, impossible, because of the limited area in which subpenas would run.

Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of container for food. One great weakness in the present food and drugs law is the absence of authoritative definitions and standards of identity except in the case of butter and some canned foods. The Government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and reputable manufacturers. The housewife makes preserves by using equal parts of fruit and sugar. The fruit is the expensive ingredient, and there has been a tendency on the part of some manufacturers to use less and less fruit and more and more sugar.

The Government has recently lost several cases where such stretching in fruit was involved because the courts held that the well-established standard of the home, followed also by the great bulk of manufacturers, is not legally binding under existing law. By authorizing the establishment of definitions and standards of identity this bill meets the demands of legitimate industry and will effectively prevent the chiseling operations of the small minority of manufacturers, will in many cases expand the market for agricultural products, particularly for fruits, and finally will insure fair dealing in the interest of the consumer.

This section also extends to all foods the present law applicable to canned foods. Under this a single reasonable standard of quality can be prescribed for any food and if the product falls below this standard it must be labeled as substandard. This provision of the present law was advocated by the canning industry in order to insure appropriate labeling of low-quality materials which too frequently were discrediting all commodities of the same class. It has operated advantageously to both producer and consumer.

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copoeial and formulary drugs by authorizing variations in strength only, whereas the present law authorizes also variations in quality and purity.

Other provisions close the loophole in the present law under which overstrength drugs, however dangerous, are not subject to regulation. A most important addition to the old law is made in the final paragraph of this section under which the distribution of drugs will be prohibited if they are dangerous to health when used in accordance with label directions.

Section 502 defines misbranded drugs and devices. In its first paragraph it makes an extremely important contribution to existing law in defining a drug as misbranded if its labeling is false or misleading in any particular. The present law contains this provision with respect to representations concerning the identity, strength, quality, and purity of the drugs, but therapeutic claims are amenable to action only if they are false and fraudulent. The persuasive effect of a false label on the consumer's mind is the same whether the representations were made in good faith or not. It has been demonstrated that effective protection of the public from falsely labeled nostrums is in many cases impossible under this language. This provision differs from that of the Senate bill (sec. 17 (a)), in that it omits the explanatory sentence:

> Any representation concerning the effect of a drug or a device shall be deemed to be false and misleading under this paragraph if such representation is not supported by persons who, by reason of scientific training and experience, are qualified as experts on the subject to which such representation relates.

It was felt that if a nostrum maker were able to obtain two or more persons who could qualify as experts and would testify in support of the label claims, the Government's case would be lost despite the fact that every competent expert in the country would unqualifiedly declare the claims to be false. The committee therefore substituted for this provision section 201 (n).

This section is also offered as a solution to a difficult legal problem. It is a well-known principle of law that a statute providing punishment for the commission of an offense must describe the offense with a reasonable degree of certainty. There are clear implications in cases arising under the old Food and Drugs Act and other laws that Congress may not, by a simple and unqualified prohibition against misleading representation, penalize the making of a representation of therapeutic effect regarding the truth of which expert opinion differs (*Seven Cases* v. *United States*, 239 U. S. 510; *United States* v. *Johnson*, 221 U. S. 488; *American School of Magnetic Healing* v. *McAnnulty*, 187 U. S. 94).

The reason for this limitation on the power of Congress is apparent. Whether the labeling of an article would be misleading and the product be thus misbranded would depend in a prosecution on whether the jury found it to be misleading.

If the Congress were to provide that a representation, about the correctness of which qualified opinion differed, would be misleading if the jury agreed with the experts holding one view but not misleading if the jury agreed with the experts holding the other view, it is apparent that the manufacturer would be unable to tell in advance whether his labeling violated the statute. There would therefore exist the kind of uncertainty which would invalidate the statute.

But it is undesirable to permit misleading claims to be made simply because a few experts can be found on the occasion of a trial to support them.

One of the important applications of section 201 (n) relates to this problem. If only a few experts regard a label statement of curative value as true but the great body of qualified experts in that particular field regard the statement as untrue, then there may be substantial ground for concluding that the curative claim is misleading unless it is qualified in such a way as to show the existence of conflicting opinion as to its truth. Certainly a consumer seeking a remedy for a disease condition has the right to know, when it is a fact, that the representations of curative value have only a narrow and limited support; and if the labeling fails to reveal that fact, which is a material fact in the light of the representations made, then the labeling may be regarded as misleading. However, the misleading character of the label may be corrected by an appropriate qualifying statement revealing this material fact.

In such circumstances, therefore, the manufacturer can easily ascertain by consulting qualified experts in the field whether there is a material weight of opinion contrary to claims he desires to make, and there would exist no uncertainty of the kind that would invalidate the statute.

Other provisions of section 502 are designed to require the labeling of drugs and devices with information essential to the consumer. The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included in this section requiring the appropriate labeling of habit-forming drugs, requiring that labels bear adequate directions for use and warnings against probable misuse, and setting up appropriate provisions for deteriorating drugs.

The section requiring appropriate warnings against probable misuse, 502 (f), differs from the corresponding Senate provision, section 17 (g). In this paragraph as it passed the Senate, a drug or device is defined as misbranded unless its labeling bears such warnings in such form and manner as may be adequate. This bill requires such warnings as are required by regulations prescribed by the Secretary. It is believed that the requirement of the Senate bill was too indefinite.

Section 503 prescribes exemptions from labeling requirements for drugs and devices similar to those provided for food when the articles are to be processed, labeled, or repacked at points other than their place of production and when, after the processing, labeling, or repacking they comply with the terms of the law. This section also provides an exemption for drugs dispensed on bona fide prescriptions. Such drugs are relieved from the requirement that the label bear the name and address of the manufacturer, the quantity of the contents, the common name of the drug, and the name of each of its active ingredients, and if the prescription is nonrefillable a warning against habit-formation. Such labeling is unnecessary for prescription drugs and, in certain cases, may have an adverse effect on the welfare of the patient.

Section 504 sets up authority for the certification of coal-tar colors used in drugs, similar to section 406 (b) relating to certification of coal-tar colors for food.

Section 505 (a) requires new drugs to be adequately tested before they are commercialized. In order to insure that the tests made have been complete, the introduction of a new drug in interstate commerce is prohibited unless the manufacturer has submitted full information showing that the drug has been adequately tested and has not been found to be unsafe for use under the conditions prescribed in the labeling. This is not a license provision, but is intended merely to prevent the premature marketing of new drugs not properly tested for safety. One recent outstanding instance of the hazards this provision is intended to safeguard against was the introduction of an untested elixir sulfanilamide, which claimed nearly 100 lives.

This provision will not put the Federal Government into the business of developing new drugs, nor will it require the Government to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for the authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market. It provides for court review of the decisions of the administrative agency adverse to the manufacturer.

Many recommendations have been received for the substitution of additional penal provisions for this section. The purpose of your committee in adopting the section as it stands is to prevent incompetent or irresponsible manufacturers from causing wholesale deaths, rather than to penalize them after the deaths have occurred.

Sections 601 and 602 define adulterated and misbranded cosmetics, respectively. They are entirely new in Federal food and drug legislation. They are designed to safeguard the consumer against injury in the use of cosmetics and to require truthful labeling.

Section 603 provides exemptions, similar to those set up for foods and drugs, for cosmetics manufactured in one place and packaged, processed, or labeled at another.

Section 604 authorizes certification of coal-tar colors for cosmetics and is similar to sections on this subject provided with respect to foods and drugs.

Section 701 relates generally to regulations. In the case of regulations, the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given and that adequate time shall be given after the promulgation of a regulation before it becomes effective.

PROCEDURE GOVERNING FORMULATION AND JUDICIAL REVIEW OF REGULATIONS

Section 701 (e), (f), and (g) of the committee amendment set forth the procedure governing the formulation and judicial review of certain regulations to be issued by the Secretary. These regulations include those with respect to the following matters: Establishing definitions and standards of identity, standards of quality, and standards of fill of container for foods (sec. 401); information on label concerning vitamin, mineral, and dietary properties of foods (sec. 403 (j)); limitations on quantity of added poisonous or deleterious substances whose presence cannot be avoided by good manufacturing practice (sec. 406 (a)); issuance of temporary permits governing manufacturing, processing, or packing so as to prevent contamination with microorganisms (sec. 404 (a)); prescribing appropriate tests on methods of

assay to determine strength, quality, or purity of drugs (sec. 501 (b)); designation of drugs as habit-forming (sec. 502 (d)); directions on label as to use of drugs (sec. 502 (f)); statements on label as to precautions necessary by reason of liability of drug to deterioration (sec. 502 (h)); and listing of harmless coal-tar colors and certification of batches thereof for foods, drugs, or cosmetics (secs. 406 (b), 504, and 604).

Such regulations are not merely interpretive. They have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported.

Hearings.—A proposal to issue, amend, or repeal any such regulation is to be made by the Secretary of Agriculture on his own initiative, or by the interested industry or a substantial portion thereof, and the Secretary is required to set the proposal for hearing. The proposal is to be set forth in general terms so that the Secretary will be free to frame the precise language of the regulation or amendment or repeal in the light of the evidence developed at the hearing.

As a result of the hearing on the proposal the Secretary may determine to issue, amend, or repeal the regulation, or not to do so. In either case, however, he is required to issue and make public an order specifying the action taken. This will prevent the pocketing of proposals to issue, amend, or repeal a particular regulation and eliminate application of the "negative order" doctrine which denies court relief where the executive officer merely fails to take any affirmative action.

If as a result of the hearing on any proposal the Secretary determines to issue, amend, or repeal the regulation, the action taken may be based only on substantial evidence of record at the hearing. Similarly, the action of the Secretary in failing to carry into effect any proposal for issuance, amendment, or repeal of a regulation set for hearing must rest on a like basis. In either instance detailed findings of the facts on which the action of the Secretary is based are required to be made public as a part of his order. It follows that if the order of the Secretary is to be valid, the Government must have placed in the record at the hearing its evidence in support of the action taken and thereby afford opportunity for persons affected to controvert viva voce the Government's evidence. While common law or jury trial rules of evidence need not be enforced at such a hearing, nevertheless it is essential to such a hearing that all the evidence on which the administrative officer acts be disclosed at the hearing and that the right to controvert viva voce be accorded. Cf. *Ohio Bell Tel. Co.* v. *Public Utilities Comm. of Ohio* (1937) 301 U. S. (preliminary print) 292.

The order of the Secretary is to take effect not earlier than 90 days after it is issued and made public, except that if the Secretary finds that emergency conditions so require, and specifies in the order his findings as to such conditions, then the order may take effect at an earlier date.

Judicial review.—Judicial review of the order of the Secretary with respect to any proposal for the issuance, amendment, or repeal of a regulation may be had in a district court of the United States.

Such review may be had on the initiative of any individual or business organization by instituting the special review proceedings pro-

vided in the committee amendment within 90 days after issuance of the Secretary's order. The complainant can institute the proceedings only in a case of actual controversy as to the validity of the order, thereby meeting the constitutional requirement for vesting in the Federal courts jurisdiction only of "cases" or "controversies."

Such review proceeding is to be instituted by filing a complaint in the district court for the district where the complainant resides or has his principal place of business. The new Rules of Civil Procedure for the District Courts of the United States which will take effect following the present session of Congress, will govern the form of complaint, service of summons, and the like. There is one exception. Personal service on the Secretary may be had anywhere in the United States even though he is without the territorial limits of the State in which the court is held.

In such special review proceeding the court will have jurisdiction to enjoin the Secretary from enforcing the order if it is invalid and may also compel him to issue an order providing for such regulation, amendment, or repeal as will be in accordance with law if justice requires that such affirmative action be taken.

Further opportunity for review of a regulation placed in effect by the Secretary will occur in criminal, injunction, libel for condemnation, exclusion of imports, or other proceedings instituted by the Government under the bill, in which the defendant is charged with violating the regulation (see secs. 302, 303, 304, and 801). If, through prior review proceedings, there has been a final determination of the validity of the regulation or order in question by the Supreme Court of the United States, or the circuit court of appeals for the particular circuit, then the question of validity would likely have become stare decisis. If, however, this is not the case, the validity of the regulation or order could be inquired into and determined in such criminal, injunction, libel for condemnation, exclusion of imports, or other proceeding.

There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.

The special type of review above outlined, where the proceedings are instituted by the individual or business organization affected, will permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and make for prompt certainty as to legal rights.

In each of the types of review proceeding above outlined the transcript of the record and proceedings before the Secretary on the proposal resulting in the order, may become a part of the evidence in the court. In the special review proceedings the Secretary is required to certify and file the transcript in the court. In the other cases, a certified copy of the transcript is required to be furnished by the Secretary and is admissible in court. The special review provisions also specifically provide that the court is to permit the private individual or concern to supplement the evidence in such transcript by adducing additional evidence (which the Secretary may rebut) bearing on the validity of the order, but only on a showing that such additional evidence is material and that there were reasonable grounds for failure to adduce

it before the Secretary. While this right to adduce additional evidence inheres in the criminal and libel proceedings originating in court, specific provision is made for it in the committee amendment in connection with the special review proceedings. The additional evidence could be taken before the court or a master, or, in the case of the special review proceeding, the court may remand the case to the Secretary for the taking of such evidence if the court deemed that desirable because of the amount of such evidence or its technical character, or in order to permit the Secretary to amend his order in the light of such additional evidence, or for any other reason.

The committee amendment is silent as to any limitations on the court in holding invalid the order of the Secretary. The court is thus left free to exercise its right of review to the full extent that it may constitutionally do so. A regulation would, of course, be invalid if the Secretary failed to observe the procedural requirements as to hearing, notice, and the like, or if the order, as specifically required by the committee amendment, was not based on substantial evidence of record at his hearing, or went beyond or was contrary to the Secretary's own finding, or to constitutional or jurisdictional limitations. Furthermore, the order would be invalid if for any other reason it was not in accordance with law. The court can take into consideration the additional evidence, if any, adduced before it, and to the extent that it may constitutionally do so, weigh the combined evidence, and hold the order invalid if in the light of such evidence it appears that the findings on which the Secretary based the order are not true in fact or that the order is unreasonable, arbitrary, or capricious.

Section 702 designates the Secretary of Agriculture as the enforcing officer and authorizes the institution of proceedings through State and local health, food, or drug officers. These provisions are the same as the present law. This section also provides that enforcing officers shall furnish a part of the sample upon which a proceeding is based to the interested parties but authorizes reasonable exemptions from this provision where the furnishing of a sample is impracticable or would defeat enforcement or would impose unreasonable expenditures of appropriations for the enforcement of the act. While no such provision as this is contained in the existing law, provision has been made in the administrative regulations for furnishing official samples.

This section also provides that records kept by other Government establishments shall be available for the purpose of enforcing this act. While this has ordinarily been done, there are certain instances where other legal restrictions have made it impossible to acquire the needed records.

Section 703 requires interstate carriers and receivers to permit access to and the copying of all necessary records to show interstate shipment and thus establish Federal jurisdiction. This provision is necessary since some warehousemen and trucking concerns and even some railroads have refused to permit the copying of records which were essential to the institution of proceedings to control abuses of consumer health and welfare. The absence of such provision in the present law has been a definite handicap to its enforcement.

Section 704 provides for the inspection of factories doing an interstate business. While no such provision is in the present law, perhaps more than 95 percent of food and drug manufacturers have invariably given permission to inspect. It is only through factory inspection

that certain abuses of consumer welfare can be established. A notable illustration of this is insanitary manufacturing conditions.

Section 705 directs the publication of the results of court actions and also authorizes the dissemination of information in situations involving imminent danger to health or gross deception of consumers. The first of these provisions is contained in the present law.

Section 706 authorizes regulations requiring the payment of fees for the purpose of certification. The fees prescribed are only such as are necessary to maintain an adequate service.

Section 801 relates to imports and contains no substantial change from the provisions of the present law.

Section 901 is the conventional separability clause.

Section 902 prescribes the effective date of the act and repeals the old Food and Drugs Act. Provisions of the new law relating to dangerous drugs, new drugs, and dangerous cosmetics, become effective at once, whereas the other provisions become effective 12 months from the date of approval. Authorization is extended for the holding of hearings and formulation of regulations to become effective on or after the effective date of the act.

CHANGES IN EXISTING LAW

In compliance with paragraph 2a of rule XIII of the Rules of the House of Representatives, the Food and Drugs Act of June 30, 1906, as amended (with the exception of sec. 10A), which is repealed by the bill, effective 12 months after the date of enactment of the bill, is set forth below enclosed in black brackets.

[AN ACT For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory of the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such articles so adulterated or misbranded within the meaning of this act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided,* That no article shall be deemed misbranded or adulterated within the provisions of this act when intended for export to any foreign country

and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this act.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform rules and regulations for carrying out the provisions of this act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry[2] of the Department of Agriculture, or under the direction and supervision of such bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

SEC. 6. That the term "drug," as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound.

SEC. 7. That for the purposes of this act an article shall be deemed to be adulterated:

In case of drugs:

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof, although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

In the case of confectionery:

If it contains terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug.

In the case of food:

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Second. If any substance has been substituted wholly or in part for the article.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*, That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this act shall be construed as applying only when said products are ready for consumption.

Sixth. If it consist in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

SEC. 8. That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this act an article shall also be deemed to be misbranded:

In case of drugs:

First. If it be an imitation of or offered for sale under the name of another article.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

In the case of food:

First. If it be an imitation of or offered for sale under the distinctive name of another article.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances contained therein.

Third. If in package form, the quantity of the contents be not plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count: *Provided, however*, That reasonable variations shall be permitted, and tolerances and also exemptions as to small packages shall be established by rules and regulations made in accordance with the provisions of section three of this act.[3]

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases:

First: In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound", "imitation", or "blend", as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term "blend" as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this act may require to secure freedom from adulteration or misbranding.

Fifth. If it be canned food and falls below the standard of quality, condition, and/or fill of container, promulgated by the Secretary of Agriculture for such canned food and its package or label does not bear a plain and conspicuous statement prescribed by the Secretary of Agriculture indicating that such canned food falls below such standard. For the purposes of this paragraph the words canned food mean all food which is in hermetically sealed containers and is sterilized by heat, except meat and meat food products which are subject to the provisions of the meat inspection act of March 4, 1907 (Thirty-fourth Statutes, page 1260), as amended, and except canned milk; the word class means and is limited to a generic product for which a standard is to be established and does not mean a grade, variety, or species of a generic product. The Secretary of Agriculture is authorized to determine, establish, and promulgate, from time to time, a reasonable standard of quality, condition, and/or fill of container for each class of canned food as will, in his judgment, promote honesty and fair dealing in the interest of the consumer; and he is authorized to alter or modify such standard from time to time as, in his judgment, honesty, and fair dealing in the interest of the consumer may require. The Secretary of Agriculture is further authorized to prescribe and promulgate from time to time the form of statement which must appear in a plain and conspicuous manner on each package or label of canned food which falls below the standard promulgated by him, and which will indicate that such canned food falls below such standard, and he is authorized to alter or modify such form of statement, from time to time, as in his judgment may be necessary. In promulgating such standards and forms of statements and any alteration or modification thereof, the Secretary of Agriculture shall specify the date or dates when such standards shall become effective, or after which such statements shall be used, and shall give public notice not less than ninety days in advance of the date or dates on which such standards shall become effective or such statements shall be used. Nothing in this paragraph shall be construed to authorize the manufacture, sale, shipment, or transportation of adulterated or misbranded foods.

SEC. 9. That no dealer shall be prosecuted under the provisions of this act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this act.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this act, or the laws of any State,

Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except, that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

SEC. 12. That the term "Territory" as used in this act shall include the insular possessions of the United States. The word "person" as used in this act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies, and associations. When construing and enforcing the provisions of this act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

SEC. 13. That this act shall be in force and effect from and after the first day of January nineteen hundred and seven.]

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75TH CONGRESS } HOUSE OF REPRESENTATIVES { REPT. 2139
3d Session } { Part 2

FOOD, DRUG, AND COSMETIC ACT

APRIL 21, 1938.—Ordered to be printed

Mr. CHAPMAN, from the Committee on Interstate and Foreign Commerce, submitted the following

MINORITY VIEWS

[To accompany S. 5]

The undersigned, members of the Committee on Interstate and Foreign Commerce, submit the following minority views with respect to one of the most important features of the bill, namely, provisions for court review of regulations of section 701 (f).

It is our view that the bill, if enacted with this review provision, will not afford any substantial improvement in consumer protection over the terms of the present law. In fact, in some respects it represents an impairment of the consumer-protective features of the present law.

Section 701 (f) sets up a method of court review of regulations that is wholly unprecedented. It is specifically provided that this method of review is in addition to, and not in substitution for, other methods of review provided by law, such as equity proceedings and proceedings under the Declaratory Judgment Act.

Regulations subject to this new form of review relate to the identity and quality of food; to requirements for informative labeling of special dietary food, such as that used by infants and invalids; to food contaminated with disease organisms where distribution might result in serious epidemics; to the addition of poisons to food; to the certification of coal-tar colors for use in foods, drugs, and cosmetics; to establishing adequate laboratory tests for important official drugs; to the listing of narcotic and habit-forming drugs; to label warnings against probable misuse of dangerously potent drugs; and to label directions for the preservation of potent drugs liable to deterioration.

These provisions constitute the very heart of any worthy food and drug legislation. If the public health and welfare are to be adequately safeguarded, regulations putting these provisions into effect should be promptly and effectively enforceable and certainly should be subject to no greater restrictions and delays in review by the courts to determine their validity than regulations authorized by other Federal laws

which deal with economic questions rather than the vital questions of public health concerned in this legislation.

Section 701 (f) permits any person who will be adversely affected by one of the regulations listed above to file, any time within 90 days after the regulation has issued, a complaint in the district court for the district where such person resides or has his principal place of business to enjoin the Secretary of Agriculture from enforcing the regulation. For example, if a regulation is issued requiring label warnings against probable and dangerous misuse of a certain class of patent medicine, then each manufacturer of that class of medicines and each dealer who profits by the sale of the medicines may file a complaint in his local district court to enjoin the enforcement of the regulation. If a single district judge could be found who would issue an injunction against such enforcement, the regulation could not be enforced at any place in the United States, even though every other district judge in the country had refused to issue an injunction. The provision would therefore clothe each and every district judge with authority to block the enforcement of a regulation throughout the United States. This is an extraordinary extension of jurisdiction and an extraordinary grant of power never heretofore seriously advanced in the entire history of the country. As suggested in the letter of the Secretary of Agriculture, a copy of which is hereto attached, if there is to be an exploration into new forms of court review of administrative regulations specifically authorized by congressional enactment, it is our conviction that such experimentation should be made in fields other than those of vitally important health laws.

Even if the injunction which blocks the enforcement of a regulation can be overturned in appellate courts, there is a provision under the preceding subsection (701 (e)) whereby the question can be reopened and the regulation again subjected to the same hazards. This provision requires that—

> the Secretary, on his own initiative, or at the request of any interested industry or substantial portion thereof, *shall* hold a public hearing upon a proposal to issue, amend, or repeal any regulation * * *. [Italics supplied.]

If the manufacturers of the class of patent medicines referred to above, or any substantial proportion of such manufacturers, demanded a public hearing on a proposal to amend or repeal a regulation previously validated by the courts after litigation under subsection (f), the Secretary would have no alternative but to hold such a hearing and to follow the prescribed procedure laid down by subsection (e) under which he would issue an order continuing the regulation in effect. The continuation of the regulation by such order would then become subject within the 90-day period prescribed, to the filing of a second crop of complaints throughout the United States. If a single district judge could again be found to issue an injunction, the regulation would again be rendered ineffective.

In most of the industries affected by the bill there are sufficient minorities, vociferously opposed to any form of regulation, to form a substantial proportion of the industry. These could be depended upon in practically every instance in which a regulation is required for the protection of public welfare to resort to the tactics above described and prevent indefinitely the effectuation of the purpose of the law.

The procedure set up in the bill to restrain the Secretary, while in form only seeming to protect industry rights, in effect amounts to the placing of the control of enforcement in the hands of those whose interests are contrary to public welfare and who have created the need for legislation.

It is true that the scope of the old law is broadened by the bill to include cosmetics, therapeutic devices, and certain drugs which are not now subject to regulation. It is true that in many instances the definitions of adulteration and misbranding have been expanded and strengthened, although even these improvements are studded with a notable number of exceptions. It is also true that the procedural provisions have been strengthened through authorization of injunction proceedings, although this, to some extent, is nullified by changes from the seizure section of the existing law, particularly that under which trial of seizure cases will in many instances occur in producing jurisdictions before juries whose sympathies would ordinarily be with local industries rather than in consuming jurisdictions where juries would be expected to display less bias.

Weighing the advantages and disadvantages for the protection of consumer welfare presented by the terms of this bill, we are unable to escape the conclusion that because of the extraordinary provision for court review of regulations in section 701 (f), which would postpone indefinitely the consumer protection that can now be afforded in some degree by the present law in much of the field to be covered by these regulations, it would be better to continue the old law in effect than to enact S. 5 with this provision.

If there is to be exploration into new methods of court review, such a radical departure from the well-established Federal procedure as is here proposed should be the subject of a separate bill, applicable to all Federal laws authorizing regulations, to be considered on its own merits. This important health legislation should not be made the sole medium for such experimentation.

Under date of March 28, 1938, the undersigned [Chapman and Mapes] submitted the then latest draft of section 701, the court-review section, of the bill to the Secretary of Agriculture and asked for his views in regard to the same.

The following is a copy of his reply:

MARCH 29, 1938.

Hon. CARL E. MAPES,
House of Representatives.

MY DEAR MR. MAPES: Receipt is acknowledged of your letter of March 28, 1938, with which you enclose a copy of chapter VII, General Administrative Provisions, section 701, from the latest edition of S. 5 as agreed upon by the Interstate and Foreign Commerce Committee of the House. You ask for an expression of my opinion of the effect of the provisions of this section upon the administration of the measure.

I am of the opinion that if section 701 (f) remains in the bill its effect will be to hamstring its administration so as to amount to a practical nullification of the substantial provisions of the bill.

The clear intent of S. 5 is to close the channels of interstate commerce to food, drugs, devices, and cosmetics that are adulterated or misbranded. Because of the complex and technical nature of the subject matter involved a number of the most important definitions of adulteration and misbranding are incomplete and must have their clearly stated outlines filled in with scientifically accurate details before they can be enforced. The bill delegates to the Secretary of Agriculture the quasi-legislative power to ascertain the necessary technical facts and supply the details that will complete these definitions, thus effectuating the legislative will.

The Secretary is entrusted with these powers in connection with sections 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (f) exclusive of the proviso, 502 (h), 504, and 604. These sections are extremely important. They relate to the identity and quality of food, to requirements with respect to special dietary food, to contaminated food, to poisonous substances in food, to coal-tar colors in food, drugs, and cosmetics, to determining adequate tests for official drugs, to narcotics and habit-forming drugs, to probable misuse of dangerously potent drugs, and to labeling drugs liable to deterioration.

Section 701 (f) permits any person who will be adversely affected by any order authorized by the sections listed above to file, any time within 90 days after the issuance of the order, a complaint in the district court for the district where such person resides or has his principal place of business, to enjoin the Secretary from placing the order in effect. This subsection contains the unique provision directing the courts to permit the complainant to supplement the evidence recorded in the Secretary's hearing upon which the order was based. This constitutes an invitation to those who would obstruct the enforcement of a regulation to withhold or conceal evidence that should have been given in the hearing and to employ such evidence merely for the purpose of upsetting the order and thus postponing indefinitely the enforcement of the regulation. In the event such order is upset there is nothing to prevent the same complainant from instituting new proceedings on a new order and thereby causing further delay. In fact, every amendment of an order could be a ground for the institution of new proceedings.

Even though a number of district courts might uphold an order, demanded alike by the public and by the overwhelming majority of the industry regulated, to terminate abusive practices, a single district court could enjoin permanently the enforcement of the regulation.

Frankly, I regard this provision as unfair to the Department, to the public, and to the industries regulated, the majority of which unquestionably would support regulations, based on substantial evidence, which the Secretary of Agriculture would promulgate. It would constitute a serious impediment to orderly administrative operations. If a bill containing this provision were enacted it would not constitute any material contribution to the public protection that the Department cannot now extend under the existing law. In some respects it would afford even less protection than that afforded by the existing law, which is broad and general in its terms and is to some degree applicable and effective in the fields covered by the sections involved in this discussion.

It is the Department's considered judgment that it would be better to continue the old law in effect than to enact S. 5 with this provision.

If there is to be exploration into new fields of administrative law, may I urge that it not be in the field of vitally important public health legislation.

There has not been sufficient time to permit the Department to ascertain the relation of the foregoing to the program of the President.

Sincerely yours,

H. A. WALLACE, *Secretary.*

Attention is called especially to the following statements in the letter of the Secretary:

I am of the opinion that if section 701 (f) remains in the bill its effect would be to hamstring its administration so as to amount to a practical nullification of the substantial provisions of the bill.

It is the Department's considered judgment that it would be better to continue the old law in effect than to enact S. 5 with this provision.

If there is to be exploration into new fields of administrative law, may I urge that it not be in the field of vitally important public health legislation.

The section as submitted to the Secretary of Agriculture was the same as the section as reported by the majority of the committee, except in two particulars, one of which weakens the enforcement provision of the section, the other of which has no effect on it one way or the other, in our opinion.

The committee amended the draft of the section as submitted to the Secretary, (1) by striking out of the committee substitute, page 82, line 19, after the word "shall", the words "if in his judgment sufficient reason appears for so doing"; and (2) by inserting, page 84, line 8,

after the word "shall", the words "upon the showing that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence at the proceeding before the Secretary."

As stated, the first amendment weakens the enforcement provision of the section. The second one requires nothing more than a court would ordinarily require without it.

If this bill is enacted into law with section 701 (f), the court-review section, in it, as reported by a majority of the committee, what started out as an effort on the part of the advocates of a more adequate food and drug law to enlarge the scope of the existing law, to fill in the loopholes in it, and to put more teeth into it, will end with having accomplished the directly opposite result and years of earnest effort will have gone for worse than naught.

VIRGIL CHAPMAN,
JERRY J. O'CONNELL,
CARL E. MAPES,
CHAS. A. WOLVERTON,
JAMES WOLFENDEN,
PEHR G. HOLMES.

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